

24 Jan 80

SUBJECT: Human Use Review of Project GRILL FLAME

1. The Office of the Army General Counsel, at the request of ACSI, reviewed Project GRILL FLAME to determine if "human use" issues were involved per Executive Order, HEW, DoD and DA guidelines, particularly AR 70-25, Use of Volunteers as Subjects of Research. On 15 Feb 79, the Army General Counsel advised ACSI (Incl 1) that:

✓ a. Project GRILL FLAME could be classified as one involving testing on human subjects.

b. Immediate contact should be established with The Surgeon General to establish a human use testing committee to review GRILL FLAME activities.

c. Current Army activities should be discontinued until The Surgeon General review was completed.

AMSAA GRILL FLAME activities ceased on 23 Feb 79 upon notification of the Army General Counsel recommendations (Incl 2).

2. In response to the Army General Counsel recommendations, a protocol for the AMSAA sponsored GRILL FLAME work was developed with the assistance of COL Garrison Rapmund, MC, Director, Walter Reed Army Institute of Research. The AMSAA protocol was presented to the Ad Hoc Subcommittee of The Surgeon General's Human Subjects Research Review Board (HSRRB) on 26 Mar 79.

3. As reported to you by LTG Pixley on 2 Apr 79 (Incl 3), the HSRRB found the AMSAA protocol to represent technology transfer and validation of the technology transfer rather than research or clinical investigation and, as such, did not require approval for human use. However, the HSRRB expressed concerns that future Army follow-on work might be classified as research and, as such, plans should be considered to provide for the following:

a. Adequate scientific review of research protocols.

b. The collaboration of behavioral scientists in execution of protocols.

c. The establishment of credible human use review processes or committees in action agencies for review of protocols.

AMSAA GRILL FLAME in-house activities and contractual efforts recommenced in Apr 79 upon notification of The Surgeon General's decision and signing of consent forms by all participants as stipulated by and included as part of the approved protocol.

REGRADED UNCLASSIFIED

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4. In June 1979, it was suggested by Dr. LaBerge, then Under Secretary of the Army, that a Scientific Evaluation Committee (SEC) be appointed to review the Army's GRILL FLAME efforts. In July 1979, Dr. Ruth Davis recommended that, because of the special interest of the Secretary of Defense, the SEC review the total DoD GRILL FLAME posture and report directly to the DoD GRILL FLAME Oversight Committee. The eight member committee was organized by the Chairman, Mr. Manfred Gale, in July 1979. It should be noted that one member of the SEC, COL Harry Holloway, MC, Professor and Chairman, Dept. of Psychiatry, Uniformed Services University of the Health Sciences, is also a member of The Surgeon General's HSRRB.

5. The MICOM GRILL FLAME program proceeded to develop the hardware required for their initial efforts and additionally developed a protocol for human use review. The MICOM protocol was presented to The Surgeon General's HSRRB 20 Nov 79. At that same time, AMSAA presented a resume of their progress to date on the AMSAA GRILL FLAME protocol, to include their ongoing efforts in response to Dr. LaBerge's tasking of May 79.

* 6. As reported to you by LTG Pixley on 11 Jan 80 (Incl 4), the HSRRB found the MICOM protocol indeed constituted research involving human subjects, although the risks to the subjects appear minimal. The HSRRB recommended the consent form for participants, as included in the MICOM protocol, be amended to include two concerns:

* a. The risks and responsibilities subjects may face if they come to believe they possess the capability to use their "powers" for personal profit.

* b. The possibility subjects may lose esteem or respect from colleagues because of the nature of GRILL FLAME activities and potentially suffer career damage.

The concerns surfaced during the previous meeting of the HSRRB, as summarized in paragraph 3 above, were again surfaced as being applicable to both the MICOM and AMSAA protocols. The HSRRB did recommend approval of the MICOM protocol pending receipt of a revised consent form which incorporates the above concerns.

7. The HSRRB felt that the ongoing AMSAA GRILL FLAME efforts appeared to involve human experimentation. Thus, in keeping with the HSRRB's recommendations on the MICOM protocol, AMSAA is now in the process of revising its consent form for participants to reflect the two specific concerns of the HSRRB as detailed in paragraph 6 above.

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DRXSY-DS

23 February 1979

MEMORANDUM FOR RECORD

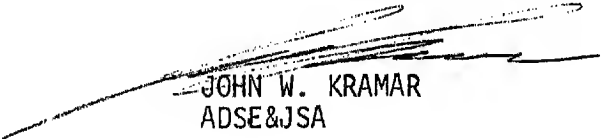
SUBJECT: Preliminary Guidance on GRILL FLAME Experiments

1. No further experiments are to be conducted until actions are taken to comply with Army guidelines on testing per reported guidance from the Army General Council. Necessary actions include:

a. Development and signing of consent forms (ADSE&JSA to obtain from ACSI).

b. ACSI to contact TSG to set up a committee.

2. More detailed guidance will be provided as it becomes available.



JOHN W. KRAMAR
ADSE&JSA

CF:
GRILL FLAME Participants

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DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
WASHINGTON, D.C. 20310

REPLY TO
ATTENTION OF

2 APR 1979

SGRD-HR

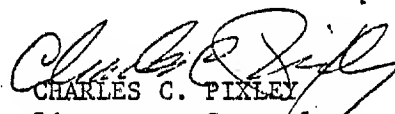
MEMORANDUM FOR GENERAL JOHN R. GUTHRIE, COMMANDER, US ARMY MATERIEL
DEVELOPMENT AND READINESS COMMAND

SUBJECT: Human Use Review of Protocols

1. Attached are the minutes of a meeting of the Human Subjects Research Review Board held to consider protocols from Stanford Research Institute and Army Materiel System Analysis Activity in Project Grill Flame.
2. It is my opinion that the specific reviewed protocols are technology transfer and phenomenology validation of the technology transfer rather than research or clinical investigation, and, as such, do not require approval for human use.
3. Anticipating future requirements, the Board expressed concern about possible follow-on research. Your attention is directed to paragraphs 3 and 4 of the minutes.

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as

CF:
USA
ACSI


CHARLES C. PIXLEY
Lieutenant General
The Surgeon General



DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
WASHINGTON, D.C. 20310

REPLY TO
ATTENTION OF:

SGRD-HR

29 March 1979

SUBJECT: Minutes of Ad Hoc Subcommittee of The Surgeon
General's Human Use Review Committee Meeting -
26 March 1979

The Surgeon General
Headquarters, Department of the Army
Washington, DC 20310

1. Under the provisions of AR 70-25 and OTSG Reg 15-2, a special meeting of an Ad Hoc Subcommittee of the Human Subjects Research Review Board (HSRRB) was convened at 1100 hours in Room 2E465 in the Pentagon on 26 March 1979 to consider human use issues of protocols presented by Stanford Research Institute (SRI) [TDSIILADREVGPL (U) - 23 March 1979] and the Army Materiel System Analysis Activity (AMSAA) [PDAAADREVGPL (U) - 23 March 1979].

a. Members present were:

COL Edward L. Buescher, MC, Chairman, HSRRB.
— COL Harry Holloway, MC, Professor and Chairman, Department of Psychiatry, USUHS, Ad Hoc Member, HSRRB.
Dr. K. E. Emerson, PhD, Consultant Ad Hoc Member, HSRRB.
Dr. Herbert L. Ley, M.D., Consultant Ad Hoc Member, HSRRB.
Dr. Chris J. D. Zarafonitis, M.D., Consultant Ad Hoc Member, HSRRB.
Ms Annie L. Young, Systems Analyst, AMSAA, Ad Hoc Member, HSRRB.
MAJ Frank Arness, JAGC, Judge Advocate, USAMRDC, and Member, HSRRB.
MAJ Richard W. Severson, MSC, C, HURO, Recorder for HSRRB.

b. Also present were:

Dr. Hal Puthoff, PhD, Stanford Research Institute, Menlo Park, CA.
Mr. Russell Targ, Stanford Research Institute, Menlo Park, CA.
— Mr. John Kramar, Assistant Director, Army Materiel Systems Analysis Activity, Aberdeen Proving Ground, MD.
COL Garrison Rapmund, MC, Director, Walter Reed Army Institute of Research, Washington, DC.

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29 March 1979

SUBJECT: Minutes of Ad Hoc Subcommittee of The Surgeon
General's Human Use Review Committee Meeting -
26 March 1979

2. Mr. Targ and Dr. Puthoff presented the SRI protocol to the Ad Hoc Subcommittee. Mr. Kramar presented the AMSAA protocol. Subsequent to discussions, the following is the unanimous consensus of the Subcommittee members:

a. The Stanford Research Institute protocol was identified as technology transfer rather than research or testing. Similarly, the Army Materiel System Analysis Activity protocol was judged to be phenomenological validation of the technology to be transferred by SRI. Descriptions of procedures and modes of evaluation are straightforward and do not present any known hazard to the persons involved.

b. For reasons stated above, Federal guidelines and Army regulations on the use of human subjects do not apply.

3. While the Ad Hoc Subcommittee judged the current protocols as other than research or clinical investigations involving human subjects, sometime in the future it is possible that follow-on work may be categorized as research, and may involve human subjects. If any follow-on research should involve human subjects, the Ad Hoc Subcommittee felt that the Army sponsors and action agencies are presently unprepared to address all anticipated problems. Specifically, the concerns include:

a. Provision for adequate scientific review of research protocols.

b. Provision for collaborating behavioral scientists in execution of protocols.

c. Provision for credible Human Use Review processes or committees in action agencies for review of protocols.


4. The Ad Hoc Subcommittee recommended that the Army sponsors and action agencies make plans to provide for solutions to the deficiencies listed in paragraph 3, above, in the event that follow-on work is planned.

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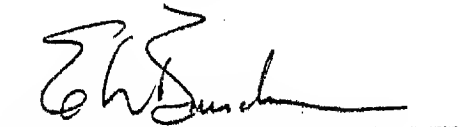
29 March 1979

SUBJECT: Minutes of Ad Hoc Subcommittee of The Surgeon
General's Human Use Review Committee Meeting -
26 March 1979


5. There being no further business, the meeting was ad-
journed at 1550 hours.


RICHARD W. SEVERSON
MAJ, MSC
Recorder

APPROVED/~~DISAPPROVED~~:


EDWARD L. BUESCHER
Colonel, MC
Chairman, Human Subjects
Research Review Board

APPROVED/~~DISAPPROVED~~:


CHARLES C. FIXLEY
Lieutenant General
The Surgeon General



REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
WASHINGTON, D.C. 20310

11 JAN 1980

SGRD-HR

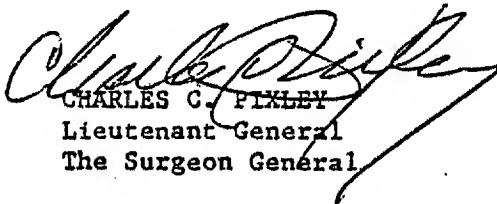
MEMORANDUM FOR GENERAL JOHN R. GUTHRIE, COMMANDER, US ARMY MATERIEL
DEVELOPMENT AND READINESS COMMAND

SUBJECT: Human Use Review of Protocols

1. Attached are the minutes of a meeting of the Human Subjects Research Review Board (HSRRB) held to consider protocols from SRI International and the US Army Missile Command in Project Grill Flame. Comments are also included on a retrospective review of the Army Materiel Systems Analysis Activity (AMSAA) study in Project Grill Flame, previously considered by the HSRRB.
2. It is my opinion that the specific reviewed protocols constitute research involving human subjects.
3. The concerns expressed previously about the use of human subjects in research studies in the Grill Flame program and delineated in the 29 March 1979 minutes of the HSRRB considering the SRI International and AMSAA protocols, are applicable to these protocols. Your attention is directed to paragraph 3b of the minutes.

1 Incl
as

CF:
USA
ACSI


CHARLES C. PIXLEY
Lieutenant General
The Surgeon General



DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
WASHINGTON, D.C. 20310

REPLY TO
ATTENTION OF

SGRD-HR

2 January 1980

SUBJECT: Minutes of Meeting of the Ad Hoc Subcommittee of The Surgeon General's Human Subjects Research Review Board - 20 November 1979

The Surgeon General
Headquarters, Department of the Army
Washington, DC 20310

1. Under provisions of AR 70-25 and OTSG Reg 15-2, a special meeting of an Ad Hoc Subcommittee of the Human Subjects Research Review Board (HSRRB) was convened at 0900 hours in Room 3E368 in the Pentagon on 20 November 1979 to consider human use issues represented in protocols presented by SRI International [Proposed Grill Flame Protocol: Task II (U) PDSIILFLFRRHONREPNTS (U) - 15 November 1979] and the US Army Missile Command (MICOM) [RPT (U) - 7 November 1979].

a. Members present were:

COL Edward L. Buescher, MC, Chairman, HSRRB.
COL Harry Holloway, MC, Professor and Chairman, Department of Psychiatry, USUHS, Ad Hoc Member, HSRRB
Dr. K. C. Emerson, Ph.D., Consultant Ad Hoc Member, HSRRB
Dr. Herbert L. Ley, M.D., Consultant Ad Hoc Member, HSRRB
Dr. Chris J. D. Zarafonetis, M.D., Consultant Ad Hoc Member, HSRRB
Ms. Annie L. Young, Systems Analyst, AMSAA, Ad Hoc Member, HSRRB
LTC Richard W. Severson, MSG, C, Human Use Review Office, USAMRDC, Recorder
CPT (P) Steven M. Porter, JAGC, Judge Advocate, USAMRDC, and Member, HSRRB

b. Observers/Investigators present were:

Dr. Billy Z. Jenkins, Ph.D., Grill Flame Principal Investigator, USAMICOM
Dr. Edward May, Ph.D., Grill Flame Project Leader, SRI International, Menlo Park, CA (contractor)
Dr. Hal Puthoff, Ph.D., SRI International, Menlo Park, CA
Dr. Russell Targ, Ph.D., SRI International, Menlo Park, CA
Mr. John Kramar, Assistant Director, Army Materiel Systems Analysis Activity, Aberdeen Proving Ground, MD

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2 January 1980

SUBJECT: Minutes of Meeting of the Ad Hoc Subcommittee of The Surgeon General's Human Subjects Research Review Board - 20 November 1979

2. Mr. Kramar presented a resume of the progress to date on the AMSAA Grill Flame Protocol [PBAAADREVGPL] (U) - 23 March 1979] dealing with phenomenological validation of technology to be transferred by SRI. The AMSAA effort began in March 1979. The following summarized committee views of the review and discussions:

a. The study has accomplished the initial objective outlined in Protocol PBAAADREVGPL (U) - 23 March 1979 and is now exploring new issues. It is clearly exceeding the validation of technology, and appears to be beyond the work scope originally examined by HSRRB and approved by TSG. The basis for this expanded scope is unclear and the current effort appears to involve human experimentation. The concerns of the ad hoc subcommittee as detailed in the previous minutes are now more relevant: "Army sponsors and action agencies are presently unprepared to address all anticipated problems. Specifically, the concerns include: (1) provision for adequate scientific review of research protocols, (2) provision for collaborating behavioral scientists in execution of protocols, and (3) provision for credible Human Use Review processes or committees in action agencies for review of protocols."

b. There clearly is no fixed and formally appointed professional oversight for work being done under "Grill Flame"; rather, oversight appears to be ad hoc, incomplete and by multiple groups, resulting in inadequate continuing assessment. Conclusions and decisions based on data generated from the research will be divergent, depending on which ad hoc group is evaluating the data; evaluating emerging evidence and deciding which evidence is worth pursuing will be an uncoordinated effort.

c. The subcommittee recommends the ad hoc supervision of the Grill Flame program be discontinued and the command responsibility for the program be identified.

3. Dr. May presented the SRI International protocol to the Ad Hoc Subcommittee. Dr. Jenkins presented the MICOM variations of the same protocol. Subsequent to discussions, the following is the unanimous consensus of the subcommittee members:

a. The SRI International and MICOM protocols do indeed constitute research involving human subjects. The immediate risks to the subjects appear to be minimal; however, there are potential latent related effects which deserve explanation in the subject consent form. Recommend the consent form be amended to include:

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2 January 1980

SUBJECT: Minutes of Meeting of the Ad Hoc Subcommittee of The Surgeon General's Human Subjects Research Review Board - 20 November 1979

(1) "You may lose the esteem or respect from certain colleagues because of the nature of Grill Flame activities since some may consider participation in such activities as indicating a belief in the 'occult or magical'. To ~~our~~ knowledge of the investigators no-one has suffered such career damage from a Grill Flame-related activity, but the potential for such is brought to your attention.

(2) "Some participating subjects may come to believe that they can possess the capacity to use _____ and/or _____ powers for personal profit in risk-taking situations (Example: participating in games of chance or speculative investment). Some individuals who have served as subjects in this kind of experiment have acted on such assumptions to their apparent disadvantage. Thus, the risk exists that you may come to believe that you have a power that you do not possess. You are advised of this risk and warned that you assume responsibility for any assumptions which you make about your personal powers or capacities."

b. The concerns expressed in the minutes of 29 March 1979 (ref. paragraph 2a above) concerning the Grill Flame program are also appropriate for these protocols and should be addressed. Responsibility seems to be divided between multiple principal investigators and direction of the program is vague and needs definition. The reviewing subcommittee felt the Army sponsors and action agencies should address the following concerning the Grill Flame program because of the public and political sensitivity of human subjects participating in such a classified project:

- (1) Scientific review.
- (2) Command and control of the Grill Flame program needs to be delineated and liability concerns properly addressed.
- (3) Public Information Offices for DA and DoD need to be knowledgeable of the ongoing and proposed work.
- (4) The Chain of Command (and responsibility) for the Grill Flame program (this protocol) from DA to DoD needs to be identified.
- (5) Security classification of the studies under the Grill Flame program is perceived to be a major impediment to continued credible scientific pursuit. If the actual R&D effort is biomedical/behavioral science, as it has been published in the open literature, the need for classification is in question. Classification of the military application of the specific science would seem appropriate.

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2 January 1980

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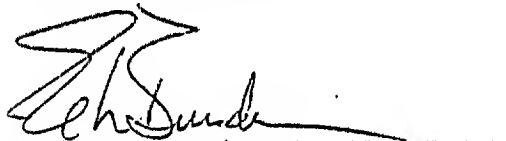
4. In addition, it was recommended that pregnant women should be excluded from participation in the work carried out under this protocol. This recommendation is in keeping with the generally prudent policy of excluding any group of subjects that might be especially sensitive to the effects of stress.

5. The ad hoc subcommittee recommends approval of the protocols pending receipt of a new revised consent form which addresses the anticipated risks mentioned above.

6. There being no further business, the meeting was adjourned at 1550 hours.

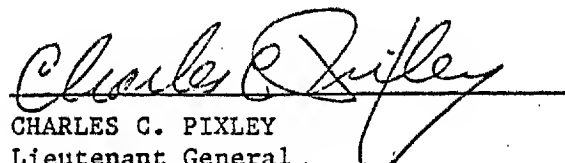

RICHARD W. SEVERSON
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